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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/834,778 | 04/12/2001 | Daniel P. Silver | 20363-011 | 3764 |

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EXAMINER

SULLIVAN, DANIEL M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1636

DATE MAILED: 05/07/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,778

Applicant(s)

SILVER ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 and 7-50 is/are pending in the application.
- 4a) Of the above claim(s) 22-50 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-17 and 21 is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-13, 18-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 12 February 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

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DETAILED ACTION

This Office Action is a reply to the "Response to Office action" filed 21 February 2003 (Paper No. 16) in response to the Non-Final Office Action mailed 21 October 2002 (Paper No. 12). Claims 1-21 were considered in Paper No. 12. Claims 1 and 6 were canceled and claims 2, 3, 5, 7, 8, 10, 14, 15 and 21 were amended in Paper No. 16. Claims 2-5 and 7-50 are pending in the application. Claims 22-50 are withdrawn from consideration. Claims 2-5 and 7-21 are under consideration herein.

Drawings

The formal drawings filed 12 February 2003 are approved.

Response to Amendment

Rejection of claims 1 and 6 is rendered moot by cancellation of the claims in Paper No. 16.

Claim Rejections - 35 USC § 112

Rejection of claims 1-21 under 35 U.S.C. 112, second paragraph, as indefinite for reasons set forth in Paper No. 12 is withdrawn.

Claim Rejections - 35 USC § 102

Claims 2, 5, 7-13 and 18-20 stand rejected under 35 U.S.C. § 102(b) as anticipated by Anderson as evidenced by Kilby *et al.* for reasons of record in Paper No. 12 and herein below in the "Response to Arguments".

Claims 2-4, 7 and 8 stand rejected under 35 U.S.C. § 102(b) as anticipated by either one of Choulika *et al.* as evidenced by Choulika *et al.* '800 or Russ *et al.* as evidenced by Kilby *et al.* for reasons of record in Paper No. 12 and herein below in the "Response to Arguments".

Claims 2, 5, 7-13 and 18-20 stand rejected under 35 U.S.C. § 102(a) as anticipated by Bunting *et al.* as evidenced by Kilby *et al.*

Allowable Subject Matter

Claims 14-17 and 21 are allowed.

Response to Arguments

In response to the rejection of claims 2, 5, 7-13 and 18-20 under 35 U.S.C. § 102(b) as anticipated by Anderson as evidenced by Kilby *et al.* Applicant has amended the claims such that they are now directed to a nucleic acid molecule comprising a first and second signal sequence that are positioned to mediate excision or inversion of either a recombinase gene or the expression control sequence when the signal sequences are contacted with a recombinase, which decreases or eliminates the recombinase-mediated toxicity. Applicant argues that Anderson does not specifically teach the excision or inversion of either a recombinase gene or an expression control sequence. Applicant asserts that the constructs cited by the Examiner do not meet the limitations of the claims because Anderson teaches the use of the constructs to specifically excise an immortalized gene and not the excision or inversion of a recombinase gene or an expression

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control sequence. Applicant argues that Anderson does not teach or suggest the use of signal sequence mediated excision or inversion of a recombinase gene or expression control sequence in order to decrease or eliminate recombinase-mediated toxicity.

These arguments have been fully considered but are not found persuasive because a recitation of the intended use or effect of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of the same effect as the claimed invention, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Applicant is claiming a nucleic acid molecule having the same structural limitations as the nucleic acid molecule taught by Anderson. Therefore, the claims are anticipated by the teachings of Anderson.

Applicant further argues that Anderson does not teach or suggest inversion of a recombinase gene or expression control sequence. Applicant's point is taken, however the claims are not limited to a vector capable of inversion of a recombinase gene or expression control sequence.

In response to the rejection of claims 2-4, 7 and 8 under 35 U.S.C. § 102(b) as anticipated by either one of Choulika *et al.* as evidenced by Choulika *et al.* '800 or Russ *et al.* as evidenced by Kilby *et al.* and the rejection of claims 2, 5, 7-13 and 18-20 under 35 U.S.C. § 102(a) as anticipated by Bunting *et al.* as evidenced by Kilby *et al.*, Applicant again argues that the teachings of the art do not anticipate the claims because the cited art does not specifically teach the excision or inversion of either a recombinase gene or an expression control sequence and

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does not teach or suggest the use of signal sequence mediated excision or inversion of a recombinase gene or expression control sequence in order to decrease or eliminate recombinase-mediated toxicity. Again, these arguments are not persuasive because recitation of the intended use or effect of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. As the nucleic acid molecules taught by the prior art meet the structural limitations of the instant claimed invention, the claims are anticipated by the teachings of the cited art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
April 25, 2003



**JAMES KETTER
PRIMARY EXAMINER**